

**REMARKS**

Entry of the foregoing, reexamination and further and favorable reconsideration of the subject application, in light of the following remarks, is respectfully requested.

By the present amendment, Claims 93 and 94 have been amended. Claims 132 - 134 have been added. No new matter enters by this Amendment. In particular, the application as originally filed discloses that peptides having the motif PTAP inhibit binding between TSG101 proteins and the Gag complex of HIV, reduce HIV particle generation., Page 9 of the specification as originally filed, lines 8 – 18. The same specification teaches administration of this peptide can reduce particle generation by half, or more. Specification, page 9, lines 14 – 16. It is further disclosed that this particle generation reduction is an effective means of treating HIV infection, and the AIDS attendant thereon. See the specification, p. 9, lines 27 – 32. With respect to Claim 132, this particular peptide, set forth in the specification at p. 16. line 12, is specifically identified as a peptide which inhibits interaction between TSG101 protein and HIV Gag. With respect to Claim 133, the importance of interfering with interaction between TSG101 and HIV in the p6 region of the Gag protein complex is set forth at p. 19 of the specification, as originally filed, lines 11 – 26. Claim 134 reflects the specific observation that critical binding appears to occur in the first 155 amino acids of TSG101 (the UEV domain). See page 28, lines 13 – 30, line 20 of the specification as filed.

**OBJECTIONS OF CLAIMS 93 AND 94**

Claims 93 and 94 stand objected due to informalities. Specifically, Claims 93 and 94 have been objected to because these claims refer to the protein TSG101 by its acronym without first identifying it by the full name, namely, tumor susceptibility gene 101 protein. Claims 93 and 94 have been amended herein to correct these informalities. Accordingly, reconsideration and withdrawal of the objections to Claims 93 and 94 are respectfully requested.

**REJECTIONS OF CLAIMS 93 AND 94**  
**UNDER 35 U.S.C. § 112, FIRST PARAGRAPH, WRITTEN DESCRIPTION**

Claims 93 and 94 stand rejected under 35 U.S.C. § 112, first paragraph, for purportedly failing to comply with the written description requirement. This rejection is respectfully traversed.

Specifically, as noted above, express support for each recitation of the claims appears in the specification as originally filed. The basis for the rejection as advanced in the outstanding office action appears to be that the breadth of the claims advanced is of such scope that it would not be possible to present a representative number of species to establish the interrelationship between form and function necessary to define the class. See the action, pages 3 – 8.

Respectfully, that analysis is not applicable to the claims presented. The claims specifically recite the required structure (the peptide exhibits the PTAP motif drawn from the TSG101 sequence, shown to achieve the desired function) and specifically recites the function essential for performance of the method claimed (inhibiting interaction between TSG101 protein and HIV Gag). The claim, as taught in the specification, goes on to indicate the specific result occurring due to this combination of structure and function. (Reduction in viral particle population leading to effective treatment of the syndrome associated with HIV infection). The examiner acknowledges that not only is this combination of structure and function advanced in the specification, but it is shown to be effective.

As the specification, as originally filed, demonstrates beyond peradventure that the inventors had clearly conceived of the specifically claimed method, using the particular peptide recited, having the function indicated, there can be no question that in fact, the written description requirement is satisfied. Withdrawal of this rejection is respectfully requested.

**REJECTIONS OF CLAIMS 93 AND 94 UNDER 35 U.S.C. § 112, FIRST PARAGRAPH, ENABLEMENT**

Claims 93 and 94 stand rejected under 35 U.S.C. § 112, first paragraph, as purportedly lacking enablement. Specifically, the specification, while being enabling for inhibiting HIV budding in cell culture by administering Gag p6 L domain comprising the PTAPP motif, is alleged to not reasonably provide enablement for other unspecified TSG-101 binding compounds

as HIV inhibitors or treatment of HIV infection or prevention of AIDS in patients. The specification purportedly does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. This rejection is respectfully traversed.

In particular, the claims as amended are not open to “unspecified TSG101 binding compounds” nor are they broadly directed to treatment of HIV infection. Rather, the claims are specifically directed to the use of a small set of peptides characterized by the functional motif, the relationship of which to the HIV Gag protein, and TSG101 protein, is fully set forth in the specification as originally filed. While these claims are not limited to the specific example acknowledged in the Action as shown to be effective, they do recite the essential characteristics of that example. The specification itself tells those of skill in the art how to arrive at related peptides, and test them for the properties required. See the specification as originally filed, page 16, line 15 – page 18, line 2.

The remaining pending claims not withdrawn, added by amendment herewith, are specifically drawn to features of the interaction between TSG101 and HIV Gag proteins illustrated for the first time by the examples and data advanced in the specification as originally filed. Again, Applicants’ claims are of a scope directed to, and reflecting, specific observed interactions. They are not confined SOLELY to the operative examples set forth in the specification, but rather, in accordance with the law, to that sphere of protection based on the observed and disclosed data that, coupled with the teaching in the specification of how to find

related peptides of the claimed invention, and how to prepare and use the same, could be arrived at without the exercise of undue experimentation. Should the examiner elect to maintain the rejection for lack of enablement, the Examiner is respectfully requested to identify that specific factor or factors, as set forth in the law, see, e.g., *In re Wands*, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) are insufficiently disclosed as to require undue experimentation. In the absence of such discussion, withdrawal of the rejection is respectfully requested.

**REJECTIONS OF CLAIMS 93 AND 94 UNDER 35 U.S.C. § 102(E)**

Claims 93 and 94 stand rejected under 35 U.S.C. § 102(e) as purportedly being anticipated by U.S. Patent Application Publication No. 2004/0109861 (**Zavitz et al.**). This rejection is respectfully traversed.

Specifically, Applicants note that as reflected in the outstanding Office Action, see the last page of Notice of References Cited, that portion composed by the Examiner, the reference to Zavits enjoys a date as a publication of June, 2004 (June 10, 2004, specifically). Even arguing for some basis in the filing papers for enablement of the claimed subject matter, as opposed to the complexes that are the subject of the reference, the effective filing date of the reference is September 15, 2003. In contrast, the claims are based on a specification which is a *continuation*, and therefore entitled to benefit of, PCT/US02/15965, filed **May 21, 2002**, more than a year in advance of the earliest-possible date of the reference. Applicants' claims are in fact entitled to

the benefit of the priority claimed in the parent PCT application, of May 21, 2001, but resolution of that claim to benefit is not required. The reference is simply not prior art to Applicants, and withdrawal of this rejection is respectfully requested.

### **CONCLUSION**

All outstanding issues have been resolved by amendment or otherwise overcome by argument. As the claims are in condition for allowance an early and favorable action thereon is respectfully requested. If the Examiner believes a telephone conference could advance prosecution of this application, the Examiner is invited to telephone the undersigned at the below-listed telephone number.

Respectfully submitted,

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